Service of the within and receipt of a copy thereof is hereby admitted this ..... day of November, A.D. 1976.

IN THE

Supreme Court of the United States

October Term, 1976
No. 75-1053

JOSEPH W. JONES, as Director of the County of Riverside, California, Department of Weights and Measures,

Petitioner,

vs.

THE RATH PACKING COMPANY, *et al.*,

Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit.

REPLY BRIEF FOR THE PETITIONER

RAY T. SULLIVAN, JR.,
County Counsel,
Riverside County, California,

LOYAL E. KEIR,
Deputy County Counsel,
3535 10th Street, Suite 300,
Riverside, Calif. 92501,

Counsel for Petitioner, Joseph W. Jones, Director of Department of Weights and Measures, County of Riverside, California.

Parker & Son, Inc., Law Printers, Los Angeles. Phone 724-6622

SUBJECT INDEX

INDEX TO APPENDICES

TABLE OF AUTHORITIES CITED

IN THE

Supreme Court of the United States

October Term, 1976
No. 75-1053

JOSEPH W. JONES, as Director of the County of Riverside, California, Department of Weights and Measures,

Petitioner,

vs.

THE RATH PACKING COMPANY, *et al.*,

Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit.

REPLY BRIEF FOR THE PETITIONER

I

Introduction.

Petitioner submits this Reply to the Brief for Respondents. Oral argument is scheduled for December 6, 1976.

The points or questions selected for comment herein are items raised in respondents' brief that are deemed by petitioner to be of particular relative importance and that need further elaboration or clarification. Other points discussed by respondents are already sufficiently treated in petitioner's opening brief.

II

Under Both State and Federal Laws, the Proper Time for Determining Accuracy of the Weight or Measure of Package Contents Is the Time of Sale to the Consumer, Not the Time of Shipment.

Simple as it may be, the foregoing is a key question in this lawsuit. Respondents state at page 20 of their brief (hereinafter Rsp. Bf.) that this is the "basic irreconcilable conflict (albeit not the only one)" in the case. However, they identify such "irreconcilable conflict" with the proposition of federal law vs. state law. Respondents contend that federal law requires accuracy at time of shipment, while state law requires accuracy at the time of sale to the purchaser, that is, the consumer or the businessman purchaser. Petitioner agrees that there is an "irreconcilable conflict." But the conflict is between petitioner and respondents, not between federal and state laws.

The weights and measures laws at issue in this case are intended to protect purchasers, both consumers and businesses, not the sellers. *United States v. Wiesenfeld Warehouse Co.*, 376 U.S. 86, 92 (1964); 15 USC 1451; 21 USC 602. Thus, it is fundamental that when such laws mandate that statements of quantity shall be accurate, they are to be accurate at time of purchase.

Both the Federal Food, Drug & Cosmetic Act and the Wholesome Meat Act provide that a food shall be deemed to be misbranded if its labeling is false or misleading in any particular or if any information required by these laws is not stated "*in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of*

purchase and use," (Emphasis added), 21 USC 343(a) and (f); 21 USC 601(n)(6).

The Fair Packaging and Labeling Act specifically declares

> "*informed* consumers are essential to the fair and efficient functioning of a free market economy. Packages and their labels should enable *consumers* to obtain *accurate* information as to the quantity of the contents and should facilitate value comparisons," (Emphasis added), 15 USC 1451; *accord*, 9 CFR 317.2(b); 16 CFR 500.7 and 21 CFR 1.8b(a).

Respondents and the Solicitor General follow the position of the Ninth Circuit that federal law does not require accuracy at time of sale, Petition, Appendix 49,[1] 51; Brief of the United States as Amicus Curiae, page 9. This position is predicated upon the erroneous premise that federal law forbids filling (or packaging) products so that they will be true weight at time of sale. Thus, respondents contend overpacking is forbidden by federal law. They cite no authority for their position; indeed there is none.

The most convincing support for the position that federal law permits overpacking so as to give accurate weight at time of sale is the fact that the American packaging industry has been doing it for years with the approval of both state and federal officials. As the Secretary of Commerce states at page 8 of the

---

[1] *General Mills et al. v. Jones*, Pet. Appendix 49: "Such practice [overpacking] would, however, violate federal law, which requires accurate weight at the time of packaging, with reasonable variations caused by gain or loss of moisture being recognized only during the course of subsequent distribution. As a result of this conflict, the California scheme cannot stand."

proposed revision of Handbook 67,[2] the *present packaging practice* is that packers overfill. "In general, packers 'target' the average quantity going into the packages far enough above the labeled quantity so that a certain large percentage of packages (70-90% is not uncommon) are equal or overfilled with respect to the labeled quantity." *Id.* at 8.

Are respondents suggesting that the long standing manufacturing practice of American industry is to be scuttled so that consumers will no longer get accurately labeled packages? Is this what Congress intended in enacting the Wholesome Meat Act, the Food, Drug & Cosmetic Act, and the Fair Packaging and Labeling Act?

We submit the following additional authorities in support of the proposition that federal law requires filling so as to give accurate weight to purchasers, and prohibits reliance on net weight "when packed":

(1) The federal regulations that recognize "reasonable variations" do not permit "reasonable shortages;" they prohibit labeling as "net weight when packed;" 9 CFR 317.2(h)(8) as to the Wholesome Meat Act; 16 CFR 500.6 as to the Fair Packaging and Labeling Act; 40 CFR 162.104(e) as to the Federal Insecticide, Fungicide, and Rodenticide Act. Likewise, 21 CFR 1.8b(f) prohibits use of any "term qualifying a unit of weight, measure or count" as to the Food, Drug and Cosmetic Act. The text of these and subsequent regulations are set forth in the Appendix hereto.

---

[2]The Solicitor General has lodged with this Court a copy of this document, which is entitled "Checking Prepackaged Commodities," National Bureau of Standards, Handbook 67 (Draft, 1975).

(2) 21 CFR 125.3(a), promulgated under the Food, Drug and Cosmetic Act, states that "reasonable variations" for vitamins in enriched flour must be "recognized" because of packaging and distribution considerations, but that this is no excuse for shortages during the shelf life of the product. Overpacking is specifically provided for.

Where overpacking is *not* permitted the regulation specifically says so. Thus, the next subsection, 125.3(b), states that overpacking of iodine content is prohibited.

(3) Another example showing that the packager is responsible for his products which change during distribution is 21 CFR 11.5(c) dealing with microbiological standards for cream pies. Are respondents to tell this Court that since they cannot control the distribution of their products, health officers can not take them off sale because of changes occurring during distribution?

(4) 21 USC 343(g) and (h)(2) provide for standards of identity and standards of fill, respectively. Starting with standard of fill, the regulations provide that for stated container sizes for a particular product the packager must pack a *minimum* net weight, 21 CFR 37.12.

The related standard of identity regulations specify the composition of the particular product. 21 CFR 15.1(a) contains the standard of identity for flour which provides that "Its moisture content is *not more than* 15 percent" (Emphasis added). The amount of moisture varies, among other reasons, depending on "the judgment of the miller" according to General Mills' technical manager, Donald Colpitts. [Single Appendix, page 29.] Thus, the amounts of solids vary

when packaged and also at time of sale from brand to brand and from lot to lot, even assuming the packager does not permit more than 15 percent moisture. [Single Appendix, page 24.] For example, one lot of General Mills flour under its Code No. D225A1 varied from minus 6 ounces to minus 20 ounces. *Id.* 24. Respondents' argument that short weight should be allowed to facilitate value comparisons is thus based on the false premise that all flour contains the same percentage of solids; it quite simply misstates the actual facts.

Other examples underlining the fallacy of respondents' premise are found in the CFR standards of identity for pasteurized processed cheese spread, skim milk cheese for manufacturing and mozzarella cheese.

21 CFR 19.775, relating to pasteurized process cheese spread, provides in subsection (a)(3):

> "The moisture content of a pasteurized process cheese spread is more than 44 percent but not more than 60 percent. . . ."

If packagers A, B, and C pack at 44, 60, and 70 percent moisture, respectively, how can a consumer decide among three packages of the product, all of which are short weight by different amounts, or even the same amount, on the basis of actual nutrition? As to flour, the Solicitor General's brief, page 4, says net weight when packed "fosters the Congressional policies of promoting fair competition and assisting consumers to make fair value comparisons among competing products. See 15 USC 1451; 21 USC 602."

How is this accomplished when packers may legally pack between 44 and 60 percent moisture, and for practical purposes may go beyond 60 percent? See also 21 CFR 19.685, skim milk cheese for manufacturing: "not more than 50 percent of moisture"; and CFR 19.600, mozzarella cheese: "more than 52 percent but not more than 60 percent of moisture".

Unlike flour, mozzarella cheese may be eaten without adding moisture. Are respondents to tell us that the shortage doesn't matter because the consumer can have a drink of water? Can cheese packagers label their products "not dried out when packed" and claim the cheese is not misbranded because only moisture has been lost and the nutrition remains?

(5) Handbook 67 (a copy of which has been lodged with the Court by the Solicitor General) states at page 1:

> "The primary object of the inspector in this field is to see that quantity is accurately represented to the ultimate purchaser—the consumer;"

The Handbook also provides on the same page:

> "Variations in quantities of packages are not permitted to such extent that the averages of the quantities in the packages comprising a lot, shipment, or delivery is below the quantity stated, and an unreasonable shortage in any individual package is not acceptable, even though overages in other packages in the same lot, shipment, or delivery compensate for such shortages. (*This is the basic quantity requirement* of the Model Regulation for

Prepackaged Commodities adopted by the National Conference on Weights and Measures *and of the Federal Food and Drug Administration.)*

(2) Perfection in either mechanical devices or human beings has not yet been attained; thus the existence of imperfection *must* be *recognized* and allowances for such imperfection must be made. These allowances *are recognized in the 'average' concept.*" (Emphasis added).

As to the *amount* of allowances for "reasonable variations" used in determining whether the lot is at least net quantity on the average, it is stated at page 8 of the Handbook:

> "(It will be noted that the suggested plus allowances are twice the suggested minus allowances at each 'labeled quantity.' *This is an acknowledgment that packers must be allowed to overfill such packages as are susceptible of moisture loss.*)" (Emphasis added.)

Ignoring the above, respondents emphasize this language from the Handbook:

> "It is admitted that such indefinites as 'ordinary and customary exposure' and 'good distribution practice' are difficult to set forth quantitatively; thus the experience and judgment of the inspector must be relied upon. He will learn to compare various environments and various systems of distribution and storage. As the result of his experience he will be able to develop procedures for conducting a sound investigation."

What this "sound investigation" refers to is the *size of the reasonable variations that should be allowed*

in computing the lot average. The quoted language has nothing whatever to do with allowing shortages below the lot average, much less shortages in every package in a lot. See Step 3 page 8, of Handbook 67, which refers to the experience and knowledge of the inspector.

Handbook 67 thus rejects the Ninth Circuit's position that net quantity is to be accurate only "when packed", and the respondents' position that net quantity is to be accurate only "when shipped", and the Handbook recognizes overpacking as a part of good commercial practice to obtain accurate weight at time of sale.

The Ninth Circuit's opinion (Pet. Appx., page 49) and the Solicitor General's brief (page 3) support net weight when packed. Respondents disagree, arguing for net weight "at the time of shipping," *i.e.*, the time when the product enters into interstate commerce (Rsp. Bf. p. 41). How can food packagers of hygroscopic products hope to overfill precisely enough so that packages will be neither overweight nor underweight when the packages are shipped days or weeks later? If accuracy must exist when packages are imported, foreign commerce in hygroscopic food products must end; there is virtually no possibility that packagers of Dutch cheese rounds, for example, can overpack exactly enough so that when the rounds are imported they will have lost just enough weight so they will be neither overweight nor underweight upon inspection at customs.

On the other hand, net weight at time of packaging, *i.e.*, before introduction into interstate commerce, would allow foreign packagers to sell more short weight than American competitors because the foreign packager has a longer distribution period during which the package will continue to lose moisture.

The foregoing authorities show that under federal law good manufacturing practice requires that the product be packed so that the label is accurate at the time and place of sale, for standards of both composition and net quantity.

If respondents hereafter will have no responsibility for label accuracy when the product is sold, on the basis of using a form of "net weight when packed" procedure, can they not claim that the product was "wholesome when manufactured" and that this terminates their responsibility to distributors, retailers and consumers? Is the milk processor to argue that, since bacteria count increases with age, it is not responsible for the quality of the milk in its packages when it is sold to a soup manufacturer, a restaurant or a consumer? Are packagers now to restrain health officers at the time and place of sale from taking their products off the market on the grounds that an administrative hearing is required first and that immediate resort to the courts is not enough? Indeed, if the health officer or the weights and measures inspector cannot look to the wholesomeness of the product and accuracy of the label statement at the time of sale, how can either of them act at all? And if they have to act on a package-by-package basis, (as stated by the Ninth Circuit, Petition, Appendix, pp. 48, 49, and 51) instead of by lots as they always have, how effective and adequate can their inspection be?[3] Peti-

---

[3]Respondents and the Solicitor General disagree (Rsp. Bf. 50; Sol. Gen. Bf. 7) with the Ninth Circuit's position (Petition, Appendix 48, 49 and 51) on package by package inspection; and in common with Handbook 67 and California's Article 5, affirm lot averaging as a proper inspection procedure.

tioner's brief stressed these practical necessities of inspection. Respondents' answer is silence.

In the *Report to the Congress By the Comptroller General of the United States,* dated April 18, 1972, entitled "Dimensions of Insanitary Conditions in the Food Manufacturing Industry" (Appendix hereto, page 6) it is stated that "FDA describes the food industry in the United States as comprising some 60,000 establishments whose output results in about $110 *billion* in purchases by consumers each year. . . . FDA has not had the money or manpower to identify promptly all the food plants operating under insanitary conditions. . . . [Appendix hereto, pages 6, 8] . . . The Congress should also be made aware that FDA *relies almost entirely on state and local governments* for inspectional coverage of some 500,000 restaurants and retail food stores that receive or ship products interstate. Inspection of these establishments by FDA to the extent necessary to judge whether such reliance is justified, would require the use of inspection resources" (Emphasis added). (Appendix hereto, p. 13.) These conclusions are confirmed by Peter Barton Hutt, Assistant General Counsel for the Food and Drug Administration in an article in the Food, Drug and Cosmetic Law Journal, March 1973, Appendix hereto. Since the Food and Drug Administration cannot even cope with adulterated food products, even with the strong support of this Court in such cases as *United States v. Dotterweich,* 320 U.S. 277 (1948) and *United States v. Park,* 421 U.S. 658 (1975), what priority can we expect the Food and Drug Administration to give to short weight? What hope would the federal agencies have of policing short weight and unfair competition under the Ninth

Circuit decision? By contrast the contemporaneous Second Circuit decision in *General Mills v. Furness,* 398 F.Supp. 151 (S.D.N.Y. 1974, aff'd, 508 F.2d 536), recognizes the compelling need for vigorous enforcement by the states under the present system.

III

California Laws and Regulations Are Neither Preempted by, nor in Conflict With, Applicable Federal Laws.

Petitioner has developed in his opening brief the proposition that the "concurrent jurisdiction" given to the states and the Secretary of Agriculture under 21 USC 678, affirms to the states their police power to order off sale packages of food products misbranded as to weight or measure of package contents. Respondents state (Rsp. Bf. 13) that such concurrent jurisdiction is limited in the sense that petitioner must follow federal, rather than state, standards of definition.

If this Court should hold, as petitioner has urged above, that the labeled net weight must be accurate at the time of sale, then there is no conflict in standards.

As this court has repeatedly held, it is only when there exists an irreconcilable conflict between state and federal laws, that the former must yield, *e.g. Kelly v. Washington,* 302 U.S. 1, 10 (1937).

The analysis with respect to the Wholesome Meat Act is not materially different than that under the Food, Drug & Cosmetic Act and Fair Packaging & Labeling Act. Thus even assuming *arguendo* that 21 USC 678 preempts conflicting state laws, if federal

law requires true weight (on the average)[4] at retail, then there is no conflict in *standards* between state and federal law. The question becomes, does the state *procedure* stand as an obstacle to achievement of the Congressional purpose? *Hines v. Davidowitz,* 312 U.S. 52 (1941).

Petitioner contends that California's standard is in full accord with the federal purpose—true weight to businessmen and consumers as purchasers.

Respondents contend that the California weight testing procedure impermissibly conflicts with the federal procedure for the reasons that (1) the State does not specifically "recognize" reasonable variations resulting from (a) good manufacturing practice, or (b) good distribution practice; (2) California uses an actual or wet tare procedure while the federal officials use a dry tare procedure; and (3) California does not order off sale overweight packages.

First, the California regulation is specifically designed to "recognize" variations, whether caused by manufacturing or distribution reasons. It does so in the same manner as Handbook 67. These variations are "recognized in the 'average concept.' Handbook 67, *supra,* pages 7, 8; Calif. Bus. & Prof. Code, 12211; Health & Safety Code, 26551; 4 Cal. Admin. Code 2930 (Art. 5).

The Ninth Circuit's opinion also acknowledges that California's Article 5 recognizes reasonable variations

---

[4]It is in this sense that the reasonable variations regulations must be interpreted. The term variation means fluctuations about a point or standard, viz., label weight, and not, as respondents contend, shortage in every package. See quotation from Handbook 67, *supra,* pages 7 and 8, stating that this is the proper interpretation of reasonable variations.

in the average concept. Pet. App. p. 48. Although the circuit court's opinion faults California for using a lot average, both respondents and the Solicitor General concur that lot averaging is proper (Rsp. Bf. p. 50 fn., Brief of the United States p. 7, fn. 4).

Second, respondents err in their contention that federal law does not require use of actual or wet tare at retail. The Food, Drug & Cosmetic Act, the Wholesale Meat Act, and the Fair Packaging & Labeling Act require that packages bear the weight of contents "exclusive of wrappers and packing substances," 9 CFR 317.2(h)(2) and 21 CFR 1.8b(q); 16 CFR 500.22, and require that statements of weight not be false or misleading and be in "such terms as will be read and understood under customary conditions of purchase and use," 15 USC 1453(b), 21 USC 343(a) and (f), 21 USC 601(n)(6), 9 CFR 301.2 (ii)(5)(ii); 301.2(ii)6; 317.2(b); 317.8(a) and 329.1. No one expects when he buys a package of, *e.g.*, respondent Rath's bacon labeled "NET WEIGHT 16 Oz.", that he is getting less than 16 oz. or that the 16 oz. includes that the wet paper (sponge) inside the package. Respondents' interpretation of the law is contrary to its terms and to its intent.

Third, to require Jones to remove from sale overweight packages is hardly a prudent or sensible enforcement procedure. Such a procedure would not help consumers and is expensive for packers; further, such a requirement is directly contrary to the instructions of the National Bureau of Standards, the agency charged by Congress with developing appropriate weights and measures enforcement procedures.

Conclusion.

American industry has adopted the Secretary of Commerce's interpretation of reasonable variations in the day-to-day operations of packaging well over 10,000 different products. What respondents ask is not merely a different interpretation of, but a drastic change in, American trade practices, which would adversely affect our farmers, businessmen and consumers.

Respectfully submitted,

RAY T. SULLIVAN, JR.,
County Counsel,
Riverside County, California,

LOYAL E. KEIR,
Deputy County Counsel,

Counsel for Petitioner, Joseph W. Jones, Director of Department of Weights and Measures, County of Riverside, California.

APPENDIX.

21 USC 343:

A food shall be deemed to be misbranded—

. . .

(g) If it purports to be or is represented as a food for which a definition and standard of identity has been prescribed by regulations as provided by section 341 of this title, unless (1) it conforms to such definition and standard, and (2) its label bears the name of the food specified in the definition and standard, and, insofar as may be required by such regulations, the common names of optional ingredients (other than spices, flavoring, and coloring) present in such food.

(h) If it purports to be or is represented as—

(1) a food for which a standard of quality has been prescribed by regulations as provided by section 341 of this title, and its quality falls below such standard, unless its label bears, in such manner and form as such regulations specify, a statement that it falls below such standard; or

(2) a food for which a standard or standards of fill of container have been prescribed by regulations as provided by section 341 of this title, and it falls below the standard of fill of container applicable thereto, unless its label bears, in such manner and form as such regulations specify, a statement that it falls below such standard.

. . .

9 CFR 317.2(h)(8):

The statement shall appear as a distinct item on the principal display panel and shall be separated by

a space at least equal to the height of the lettering used in the statement from other printed label information appearing above or below the statement and by a space at least equal to twice the width of the letter "N" of the style of type used in the quantity of contents statement from other printed label information appearing to the left or right of the statement. It shall not include any term qualifying a unit of weight, measure, or count such as, "jumbo quart," "full gallon," "giant quart," "when packed," "Minimum" or words of similar import.

16 CFR 500.6(b):

The declaration of net quantity shall appear as a distinct item on the principal display panel, shall be separated (by at least a space equal to the height of the lettering used in the declaration) from other printed label information appearing above or below the declaration and, shall not include any term qualifying a unit of weight, measure, or count such as "jumbo quart," "full gallon," "when packed," "minimum," or words of similar import. . . .

21 CFR 1.86(f):

The declaration shall appear as a distinct item on the principal display panel, shall be separated (by at least a space equal to the height of the lettering used in the declaration) from other printed label information appearing above or below the declaration and (by at least a space equal to twice the width of the letter "N" of the style of type used in the quantity of contents statement) from other printed label information appearing to the left or right of the declaration. It shall not include any term qualifying a unit of weight, measure, or count (such as "jumbo quart" and "full gallon")

that tends to exaggerate the amount of the food in the container. . . .

21 CFR 11.5:

(a) For the purposes of this section a frozen ready-to-eat banana, coconut, chocolate, or lemon cream-type pie is a frozen ready-to-eat pie that is labeled as and/or has the physical and compositional characteristics of a cream-type pie, including but not limited to semi-solid filling and/or topping, and contains flavoring and/or fruit ingredients corresponding to the banana, coconut, chocolate, or lemon flavor representation made for such pie. It is made with or without a crust.

(b) A sample of a frozen ready-to-eat banana, coconut, chocolate, or lemon cream-type pie, as defined §11.2(b) when examined by the methods described in sections 41.015 and 41.016 of the "Official Methods of Analysis of the Association of Official Analytical Chemists" 11th Ed. (1970), shall meet standards of microbiological quality as follows:

(1) Aerobic plate count (geometric mean) ≤50,000 per gram.

(2) Coliform count (geometric mean) ≤50 per gram, MPN.

(c) If the microbiological quality of the cream-type pies described in paragraph (a) of this section falls below the standard prescribed by paragraph (b) of this section, the label shall bear the statement of substandard quality specified in § 11.1(b)(1)(i).

21 CFR 15.1(a):

Flour, white flour, wheat flour, plain flour, is the food prepared by grinding and bolting cleaned wheat, other than durum wheat and red durum wheat. . . .

Its moisture content is not more than 15 percent. . . .

21 CFR 37.12:

(a) The standard of fill of container for canned salmon, based on a 24-can average, is a fill including all the contents of the container and is not less than the minimum net weight specified for the corresponding can size in the following table:

I. *Can size*	II. *Minimum net weight*
603x405	64 oz. (4 lb.)
301x411	16 oz. (1 lb.)
301x408	15½ oz.
401x211	15½ oz.
607x406x108	15½ oz.
301x308	12 oz.
307x200.25	7¾ oz.
513x307x103	7¾ oz.
307x113	6¾ oz.
301x106	3¾ oz.
407x213x015	3¾ oz.

If the can size in question is not listed, calculate the value for column II as follows: From the list, select as the comparable can size, that one having the nearest water capacity of the can size in question, multiply the net weight listed in column II by the water capacity of the can size in question, and divide by the water capacity of the comparable can size. Water capacities are determined by the general method provided in § 10.6(a) of this chapter.

(b) If canned salmon falls below the standard of fill or container prescribed in paragraph (a) of this section, the label shall bear the general statement of substandard fill specified in § 10.7(b) of this chapter, in the manner and form therein speciried.

21 CFR 125.3:

(a) If a food purports or is represented to be for special dietary use because of vitamin or mineral properties, the label shall bear a statement of the percentage of the U.S. RDA of such vitamins and minerals, as set forth in § 125.1(b), supplied by such food when consumed in a specified quantity during a period of 1 day. The quantity specified shall be a reasonable quantity suitable for and practicable of consumption within 1 day. The order in which the nutrients appear on the label shall be in the order listed in § 125.1(b), except when other regulations indicate otherwise. Immediately preceding the declaration of vitamin and mineral content, the following heading shall be stated, "Percentage of U.S. Recommended Daily Allowances (U.S. RDA)". If such purported or represented special dietary use is for persons within one or more groups for which the recommended daily allowance is set, such statement shall include the percentage for each age groups. When such proportion or percentage is a whole number and a fraction or a whole number and a decimal, it shall be expressed as the whole number disregarding the fraction or decimal. The total quantity of vitamins or minerals in a food shall be no less than the amount declared, and no more than a reasonable amount above the declared quantity. Reasonable variations caused by heat, light, oxidation, storage, transportation, or unavoidable deviations in good manufacturing practice are recognized.

(b) The requirements of this section shall not apply to iodized salt, when the declared content of the iodine compound in the salt is equivalent to 0.01 percent by weight iodine.

40 CFR 162.104(e):

Allowance for loss. A statement of net content "when packed" does not comply with the requirements of the act. The statement must be such that it will be correct as long as the economic poison is subject to the law. Thus, if a product such as borax may lose weight by drying out when stored in paper bags, it must be packed and labeled in such a way that the statement of net content will be correct when the product is purchased.

Report to the Congress. Dimensions of Insanitary Conditions in the Food Manufacturing Industry. Food and Drug Administration, Department of Health, Education, and Welfare, by the Comptroller General of the United States. [April 18, 1972, pages 1 to 5.]

[Letterhead]

DIGEST

WHY THE REVIEW WAS MADE

The Food and Drug Administration (FDA) is required, by law, to provide assurance that food products shipped across State borders—which includes most of the foods purchased by the American people—are processed under sanitary conditions and are safe, pure, and wholesome to eat.

The General Accounting Office (GAO) wanted to know whether FDA was able to provide this assurance. FDA describes the food industry in the United States as comprising some 60,000 establishments whose output results in about $110 *billion* in purchases by consumers each year.

FDA's inventory of establishments subject to inspection includes about 32,000 food manufacturing and process-

ing plants. FDA inspects such plants to determine whether their products meet requirements of the Food, Drug and Cosmetic Act (FD&C Act). FDA's inventory includes also about 28,000 establishments of other types, such as storage facilities and repacking and relabeling plants. It excludes restaurants, retail stores, and meat and poultry slaughtering and processing plants.

To assess sanitary conditions in the food manufacturing industry, GAO requested FDA to inspect 97 food manufacturing and processing plants selected at random from about 4,550 food manufacturing and processing plants in six FDA districts including 21 States. (See pp. 19 and 20.)

GAO auditors accompanied FDA inspectors on their inspections of 95 of the plants.

The 97 plants had annual sales of about $443 million.

They manufactured or processed bakery products, candy, fish, flour, carbonated beverages, cheese, ice cream, fruits, vegetables, popcorn, chips, sugar, jams and jellies, macaroni, pizzas, spices, etc.

This report has two basic purposes: (1) to show the dimensions of insanitary conditions in the food manufacturing industry and (2) to suggest ways to improve the FDA's management of the program which is intended to ensure compliance by the industry with standards of sanitation required by the FD&C Act. Conditions believed to exist in the industry have been projected through the use of statistical sampling techniques. Therefore it would not be equitable to single out by name the 97 plants visited from the 4,550 plants which formed the basis for the statistical projection. Accordingly the plants have not been identified in the report.

FINDINGS AND CONCLUSIONS

Overall findings

During the past 3 years, FDA inspections have indicated that sanitary conditions in the food industry in the United States are deteriorating. FDA did not know how extensive these insanitary conditions were and therefore could not provide the assurance of consumer protection required by the law.

A serious problem of insanitary conditions exists in the food manufacturing industry. Several actions must be taken by FDA to alleviate these conditions.

Existing conditions

Of the 97 plants included in the sample, 39, or about 40 percent, were operating under insanitary conditions.

Of these, 23, or about 24 percent, were operating under serious insanitary conditions having potential for causing, or having already caused, product contamination.

Photographs of conditions at some plants, taken during FDA-GAO inspections, and detailed descriptions of some of the inspection results, will be found in chapter 2.

On the basis of the sample, GAO estimated that 1,800, or about 40 percent, of the 4,550 plants were operating under insanitary conditions, including 1,000, or about 24 percent, operating under serious insanitary conditions.

FDA officials advised GAO that conditions at plants located in the 21 States would, in their opinion, be representative of conditions at plants nationwide.

Inspection manpower

FDA has not had the money or manpower to identify promptly all the food plants operating under insanitary conditions. During the last 3 years, FDA has sharply reduced its sanitation inspection coverage of food plants in an attempt to cope with more critical problems, such as microbiological contamination and drug hazards.

FDA has a management improvement program under way to develop a system for improving the effectiveness of its field operations. (See p. 31.)

Although it has a responsibility under the FD&C Act, FDA generally does not inspect restaurants and other retail food stores but relies instead on State and local officials for this regulation. (See p. 25.)

According to officials of the Department of Health, Education, and Welfare (HEW), the President, HEW, and FDA have recognized the need to increase and improve the inspection capability of FDA to make an effective impact upon present insanitary conditions of the food manufacturing industry.

Enforcement

In several instances of insanitary conditions found during plant inspections, GAO noted a need for more timely and aggressive enforcement action by FDA.

In 14 of 111 enforcement actions reviewed, or 13 percent, the action to correct the problem was inadequate for a variety of reasons. (See p. 35.)

Although judgment is involved in selecting the appropriate actions in each case, criteria or guidelines are needed to assist the FDA districts in making these decisions, particularly for repeated violators.

Causes of conditions

Although responsibility for sanitation rests with the food manufacturers, GAO believes that factors contributing to the poor sanitation conditions in the industry are (1) FDA's limitation in resources to make inspections and (2) lack of timely and aggressive enforcement actions by FDA when poor sanitation conditions are found.

During fiscal year 1972 FDA plans to inspect about 9,400 food establishments and has 210 inspectors to do the job. The planned number of inspections clearly is inadequate to detect all insanitary establishments.

FDA's inventory of food manufacturers for planning inspections and measuring the scope of its plant inspection responsibility was not complete or accurate. For six FDA districts, 22 percent of the plants listed were out of business, 8 percent were misclassified as food manufacturers, and 6 percent were not an FDA inspection responsibility.

FDA officials told GAO that there are food plants in existence which may not be on its inventory because, in the absence of plant registration requirements, FDA does not have an effective means of identifying all food plants subject to the FD&C Act. (See p. 19.)

More effective use of consumer complaints, an accurate inventory of food plants subject to inspection, and data indicating the effectiveness of inspections and regulatory actions could contribute to improving sanitary conditions of the food manufacturing industry.

FDA should (1) notify violators officially of sanitation standards violated, (2) request a prompt reply, and (3) monitor cases to promote corrective action. Without

these actions, plants may continue to disregard sanitation standards, making reinspections necessary to determine whether corrective actions have been taken. (See p. 40.)

Providing in the law for civil penalties (fines) for violations of the FD&C Act would allow FDA more flexibility in enforcing sanitation standards. (See p. 40.)

Consumer complaints

FDA is devising a computerized system to record consumer complaints to identify industry and product problem areas. The output of the system, in GAO's opinion, should be used also to monitor the disposition of such complaints.

Insanitary products that had reached the consumers might have gone undetected by FDA for some time had not the consumer complained.

RECOMMENDATIONS OR SUGGESTIONS

GAO recommends that the Secretary, HEW, direct FDA, to:

—Periodically select and inspect a representative number of food plants to assess industrywide conditions and report its assessments to the Congress.

—Periodically evaluate the accuracy of the inventory of food plants to be inspected so that FDA will know the scope of its responsibilities and resources needed for sanitation inspections. FDA should provide this data to the Congress for the same reason.

—Establish milestones for implementing its management improvement program for using statistical techniques to identify problem areas, allocate resources, and measure the effectiveness of its regulatory actions.

—Monitor the implementation of the improvement program and advise appropriate congressional committees periodically on the progress being made in, as well as the various levels of resources needed for, implementing the program; and develop an interim plan of action, pending the completion of this program, for consideration by the Congress.

—Establish criteria for the districts to use in determining (1) when more aggressive action should be taken against plants that violate good manufacturing practice regulations and (2) what type of action should be taken.

—Take a stronger enforcement posture against those plants that show continuing flagrant disregard of the FD&C Act.

—Issue written notices in all cases of plants not complying with the FD&C Act and request written responses on actions taken or planned to correct the violations and to ensure continued compliance.

—Obtain feedback on the disposition of all cases referred to State or other regulatory bodies for corrective action.

—Implement a uniform system for recording consumer complaints to monitor the disposition of complaints at the local level and to provide headquarters' officials with a means of identifying industry and product problems affecting more than one district.

AGENCY ACTIONS AND UNRESOLVED ISSUES

GAO submitted a draft of this report to the Secretary, HEW, for comment. The views of FDA and HEW were discussed with GAO and included in the report. HEW concurred in GAO's recommendations and advised that a number of corrective actions had been

or would be taken. (See pp. 17, 22, 32, 40, and 44.)

MATTERS FOR CONSIDERATIONS BY THE CONGRESS

In the light of the insanitary conditions shown to exist in the food manufacturing industry, the Congress should, upon receipt of a more accurate inventory of food plants under FDA's jurisdiction and an interim plan of action, consider the adequacy of FDA's inspectional coverage of food plants with the resources available under its current appropriation.

The Congress should also be aware that FDA relies almost entirely on State and local governments for inspectional coverage of some 500,000 restaurants and retail food stores that receive or ship products interstate. Inspections of these establishments by FDA to the extent necessary to judge whether such reliance is justified, would require the use of inspection resources.

To attain additional flexibility for enforcing the FD&C Act, the Congress should consider amending the law to provide for civil penalties when food sanitation standards are violated.

Food, Drug and Cosmetic Law Journal
March, 1973—pp.178, 180-181.

PHILOSOPHY OF REGULATION UNDER THE FEDERAL FOOD, DRUG AND COSMETIC ACT

By PETER BARON HUTT

Mr. Hutt Is Assistant General Counsel for Food and Drugs, Department of Health, Education, and Welfare. His Paper Was Presented at the Food and Drug Law Institute—Food and Drug Administration Sixteenth Annual Educational Conference in Washington, D. C. on December 12, 1972.

. . .

. . . [A]s long as any official is charged with the enforcement of this statute, he must and will continue to exercise enormous discretion in its administration.

Impossible to Regulate All Industries

Just one example will suffice to illustrate this point. It is outside the realm of possibility, either now or in the foreseeable future, for the Food and Drug Administration fully to enforce every provision of the Act. One simply cannot achieve optimal regulation of a highly inventive $135 billion a year group of industries on a budget of $164 million. Indeed, the entire budget of the Food and Drug Administration could undoubtedly be devoted to the enforcement of any of a number of individual subsections of the Act without achieving full enforcement of even that limited provisions. As a matter of practical necessity, therefore, we must set priorities and develop programs designed to achieve the greatest impact possible from the limited resources available. This unquestionably means that worthwhile projects and programs, and even entire sections of the law, will receive inadequate attention.

. . .